UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 22, 2005

MEMORANDUM

SUBJECT: Efficacy Review for Sterilex Ultra Disinfectant Cleaner Solution1,
EPA Reg. No. 63761-8;
DP Barcode: D318415

FROM: Lorilyn M. Montford LM 9/22/05
Efficacy Evaluation Team
Antimicrobial Division (7510C)

TO: Marshall Swindell, PM 33/Karen Leavy
Regulatory Management Branch I
Antimicrobial Division (7510C)

THRU: Nancy Whyte, Acting Team Leader
Efficacy Evaluation Team
Antimicrobial Division (7510C)
22, 2005

APPLICANT: Sterilex Corportation
11409 Cronhill Drive Suite L
Owings Mill, MD 21117

Formulation From Label:

Active Ingredient(s)	% by wt
n-Alkyl (C12 68%, C14 32%,)dimethyllethylbenzyl ammonium chloride	3.00%
n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethylbenzyl ammonium chloride	3.00%
Hydrogen perioxide	6.30%
Inert Ingredient(s)	87.70%
Total	100.00%

I BACKGROUND

In this submission the applicant, Sterilex Corporation, is requesting an amendment to the label to add a claim against *Zygosaccharomyces bailii*, and to add directions for use against *Zygosaccharomyces bailii*. The submitted study, MRID No. 465610-01 was conducted at ATS Labs which is located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. The study was completed on June 30, 2004. Sally Nada, B.S. is listed as the Study Director.

The test substance used in this study is Ultra-Kleen Solution 1. This product is substantially similar to the proposed product, Ultra Disinfectant Cleaner Solution 1.

This data package contained a letter from the applicant, dated June 1, 2005, three copies of the study (MRID 465610-01, three copies of the revised product label, and a revised data matrix for each active ingredient. Statement of No Data Confidentiality Claim for the study is also included.

II USE DIRECTIONS

Sterilex Ultra Disinfectant Cleaner Solution 1 is one part of a two-part product. It must be used in conjunction with Sterilex Ultra Activator Solution. When mixed with the activator this product is a one-step, hospital disinfectant at a dilution of 12 fl. Oz. Per gallon. Bactericidal according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus 5% organic serum.

The product is designed to be used on washable, hard, non-porous surfaces in hospitals, medical and dental offices, nursing homes, health care facilities, ultrasonic baths, federally inspected food processing facilities, federally inspected meat and poultry plants, wineries, breweries, dairy farms, swine farms, kennels, pet animal quarters, zoos, pet shops, animal laboratories, public restrooms, food storage businesses, restaurants, and schools.

Add 12.8 oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. tap water in an appropriate plastic container and stir. Thoroughly wet surfaces with the use solution by pouring, wiping, brushing, scrubbing, spraying, with a course trigger sprayer, sponging, using a clean in place system, pumping it through the system, drawing it through the system or mopping. Allow surfaces to remain wet for at least 10 minutes. Rinse all surfaces thoroughly with a potable water rinse.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Supplemental Claims

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 465610-01 "AOAC Use Dilution Method for "Sterilex Ultra Disinfectant Cleaner Solution 1". Study conducted at ATS Labs by Sally Nada, B.S. Study completion date – June 30, 2004

This study was conducted against *Zygosaccharomyces bailii* (ATCC 56075). Two lots of the product and activator (Lot Nos. 3A225 and 3A320) Ultra-Kleen Solution 1 and 2, and two lots of product and activator (Lot Nos. CH2842200 and CH2842400) Ultra Kleen Solution 1 and 2, were tested using the AOAC Use Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The use solution was made by adding 6mL of product and 6mL of activator to 188 mL of AOAC Synthetic Hard Water. A culture of *Zygosaccharomyces bailii* was prepared by using a stock culture to create a 0.05 McFarland turbidity broth culture Butterfield's Buffer. The suspension was used to make a lawn of growth by adding 0.2 mL of this suspension to agar plates and incubating 2-3 days at 20-25°C. Following incubation,3-7 mL of sterile diluent/medium was transferred to each agar plate and swabbed to suspend the organisms. A 1.3 mL aliquot of FBS was added to 24.7 mL of the test organism to yield a 5% fetal bovine serum soil load. The penicylinders were transferred to the culture and immersed for 15 minutes at a ration of 1 carrier per 1.0 mL culture. Penicylinders were then dried on filter paper in a sterile petri dish at 35-37°C for 40 minutes and 69.9% humidity. For each prepared test substance, 10 contaminated and dried carriers were individually transferred by hook needle at staggered intervals to individual tubes containing 10mL of the prepared test substance at the requested dilution and exposed for 10 minutes at 20±1°C. Following exposure, each exposed carrier was then transferred by gook needle at identical staggered intervals to 10mL of Letheen Broth with 0.05% catalase between 30-60 minutes following the first transfer. Controls included purity, organic soil sterility, carrier sterility, neutralizing subculture medium sterility, viability, neutralization confirmation, and carrier population

V RESULTS

Test Substance	Test Organism	Date Performed	Sample Dilution	Number of Carriers	
				Exposed	Showing Growth
Ultra-Kleen Solution 1, Lot 3A225 and Ultra_Kleen Solution 2, Lot 3A230	Zygosaccharomyces bailii (ATCC 56075)	9/3/04	30 mL Ultra-Kleen Solution 1 + 30 mL Ultra Kleen Solution 2 diluted to 1000mL	1°= 10 2°=10	1°=0 2°=0
				1°= 10 2°=10	1°=0 2°=0

1° Primary subculture
2° Secondary subculture

VI CONCLUSIONS

1. Under the conditions of the study, in the presence of a 5% fetal bovine serum organic soil load, Ultra-Kleen Solution 1,(Lot 3A225)and Solution 2 (Lot 3A230), demonstrated efficacy against *Zygosaccharomyces bailii.*

2. Under the conditions of the study, in the presence of a 5% fetal bovine serum organic soil load, Ultra-Kleen Solution 1 (Lot CH2842200 and Solution 2 (Lot CH2842400), demonstrated efficacy against *Zygosaccharomyces bailii.*

VII RECOMMENDATIONS

1. The label claims (as supported by MRID 465601-01) are acceptable regarding the use of the product, Sterilex Ultra Disinfectant Cleaner Solution1, on washable, hard, non-porous surfaces as a disinfectant against Zygosaccharomyces bailii with a contact time of 10 minutes.